lumen at said distal end and providing a fluid flow path between said first and second ~~lumen~~.

B2 Cancel

REMARKS

We are in receipt of the Office Action dated January 23, 2002, and the accompanying Amendment and following remarks are made in light thereof.

Claims 19-22 and 38-40 are pending in the application. Pursuant to the Office Action, Claims 19 and 38 are rejected for anticipation under 35 USC 102(e) over Waksman et al. 5,899,882; Claim 20 is rejected for obviousness over Waksman et al. and Bressler et al. 5,466,223; Claim 21 is rejected for obviousness over Bagaoisan et al. 5,498,240 and Bennett 4,838,881; Claim 22 stands rejected for obviousness over Bagaoisan et al., Bennett and Waksman et al.; Claim 39 stands rejected for obviousness over Waksman et al. and Ressemann et al. 5,395,332; and Claim 40 stands rejected for obviousness over Waksman et al. and Mawad 5,498,227. Claim 20 also stands rejected under 35 USC 112 for indefiniteness. This rejection has been addressed in the present Amendment by changing the dependency of Claim 20 from 18 to 19.

Turning first to the rejection of Claim 19 for anticipation over Waksman et al., Claim 19 is directed to a catheter for use in a intraluminal treatment system including a transfer device with a central opening for receiving the catheter. The claim, written in

Jepson format, requires the catheter to have an integral connector with at least one detent for securing the connector in the central opening of the transfer device, with the detent being manually actuable to release the catheter from the central opening. This feature is shown in Fig. 41C and described on page 33, lines 20-33 of the Specification as follows:

> The central plug portion 386 of the connector 364 includes two integral, radially-opposed cantilever arms 396 that are connected to the distal end of the central plug 386 and extend axially along, but spaced away from, the central plug portion. The proximal ends of the arms 396 include transverse detent tabs 398 that, when the connector is inserted into the transfer device, snap into contact with a protecting shoulder 400 (Fig. 32C) in the distal end of the transfer device, thus securing the connector in place. To disengage the connector from the transfer device, the cantilever arms 396 must be depressed radially inwardly to allow the detent tabs 398 to clear the shoulder 400. Simultaneously, the release button 318 must be depressed to disengage the release switch 358 from the connector.

See also Fig. 58A and page 55, lines 31 and following, which illustrate and describe connector 588 with detents 626. As no such structure is shown or described in Waksman et al., the rejection of this claim for anticipation over Waksman et al. is improper.

Claim 20 is rejected for obviousness over Waksman et al. in view of Bressler et al. Claim 20 is dependent from Claim 19 and requires the detent on the catheter to comprise the cantilever arm axially extending from the connector. As characterized by the Examiner, Waksman et al. discloses "a detent in the center of the transfer device", while Bressler et al. discloses "a needle

assembly which includes both a detent and a cantilever arm" in which the "cantilever allows for a snapping motion which provides an audible indication to the user that the locking had taken place."

Applicant is unsure as to exactly what structure the Examiner is referring to when Waksman et al. is cited for showing a detent. Waksman et al. described at Col. 23, Lns. 65- Col. 24, Ln. 4 a "detent ball 437" that cooperates with the fluid control switch 421. However, there is nothing in Waksman et al. about a detent associated with the catheter.

Bressler et al. discloses a needle guard or barrier that has an elongated arm 37 that prevents unintended needle sticks. The Examiner does not elaborate on how this needle barrier can be combined with Waksman et al. to achieve the claimed cantilever detent for the catheter called for in Claim 20. However, applicant believes that such is obtainable only through a strained use of hindsight based upon the teachings of the present application. Accordingly, applicant submits that Claim 20 is not rendered obvious by the cited references.

Claim 21 is directed to a catheter for use in an intraluminal treatment system with first and second lumens that utilizes pressured fluid to move a treatment element between the proximal and distal ends of the catheter. The second lumen is required to have an elliptical cross section. The elliptically-shaped lumen is

the fluid return lumen 434 described in the Specification on page 35, lines 23-30 and shown in Fig. 42D. See also lumen 650 in Fig. 58B.

The Examiner asserts that the Claim 21 is obvious over the combination of Bagaoisan et al. and Bennett. Bagaoisan et al. is cited merely for showing a multi-lumen balloon catheter. Bennett is cited for shown elliptically-shaped lumens.

Bennett discusses various cross sectional shapes for the lumens of a catheter and concludes that circular lumens do not optimize the use of available area and catheters having circular cross sections. Bennett states that semi-circular or wedge-shaped lumens optimize the use of available area, but have "dead spaces and stagnation areas in the fluid flow at the junctures between the surfaces." Bennett concludes that elliptically-shaped lumens eliminate the fluid flow problems of the semi-circular and wedge-shaped lumens and use the catheter cross section area more efficiently than circular lumens. Nevertheless, Bennett concludes that the preferred cross-section for the lumens is circular, and, as seen in Fig. 5, each of the IV tubes 20a, 20b and 20c has a circular cross section. Thus, applicant respectfully submits that Bennett teaches away from the claimed invention and that the combination of Bagaoisan et al. and Bennett does not render Claim 21 unpatentable.

Claim 22 is dependent from Claim 21 and calls for a radiopaque marker band located within the first lumen (which receives the treating element) at the distal end of the catheter. This is described in Specification on page 57 at lines 13-19, which describe an intraluminal connector 646 made of platinum/iridium so as to be visible under flouroscopy. See also Fig. 58C. To emphasize this aspect of the invention, Claim 22 has been amended to also require the radiopaque marker to provide a fluid flow path between the first and second lumens.

The Examiner asserts that Claim 22 is unpatentable over Bagaoisan et al. and Bennett, as applied to Claim 21, and further in view of Waksman et al. The deficiencies of Bagaoisan et al. and Bennett is applied to Claim 21 are set forth above. Since Claim 21 is patentable, Claim 22 is also patentable. However, Claim 22 is also independently patentable. The Examiner cites Waksman et al. for teaching a radiopaque tip plug bonded to the ends of the inner and outer tubes. The molded tip plugs cited by the Examiner is designated 250 in Fig. 9, and is described in Col. 18, Ln. 64-Col.19, Ln. 5. However, the tip plug is not located within said first lumen at said distal end of catheter nor does it provide the fluid flow path between the two lumens as required by Claim 22, as amended. Indeed, this aspect is neither disclosed nor suggested by Waksman et al. Accordingly, applicant submits that Claim 22 is not rendered unpatentable by the references cited by the Examiner.

Claim 38, like Claim 19, is also rejected for anticipation over Waksman et al. Claim 38 is directed to a catheter for use in an intraluminal treatment system. The catheter has three lumens, one of which is sized to receive a guidewire. Importantly, this lumen is required to have a lining that resists damage from the guidewire as the catheter is delivered over the guidewire to the treatment site. This is described in the Specification on page 36, lines 21-26 and shown in Fig. 42C. As there is no discussion or suggestion in Waksman et al. that the guidewire lumen include a lining, the rejection of Claim 38 for anticipation over Waksman et al. is improper.

Claim 39 is dependent from Claim 38 and requires the guidewire lumen lining to comprise a high density/low density polyethylene. The Examiner rejects Claim 39 over Waksman et al. in view of Ressemann et al. The Examiner cites Ressemann et al. for disclosing a catheter utilizing "density polyethylene," citing Col. 8, Lns. 8-11. However, the text cited by the Examiner indicates only that one segment of the catheter, the second tubular segment 72, "is a thermoplastic, such as high density polyethylene." However, segment 72 does not even include either a guidewire lumen or a lining of any sort, let alone a guidewire lumen having a lining to prevent damage to the lumen. Further, "high density polyethylene" is not the same as, nor does it suggest the use of, high density/low density polyethylene as required by Claim 39.

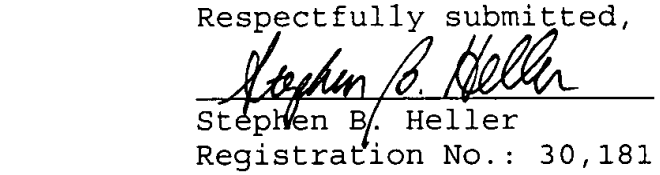
Accordingly, applicant submits that Claim 39 is not rendered unpatentable over Waksman et al. and Ressemann et al.

Claim 40 is directed to a catheter for use in an intraluminal radioactive treatment system in which the catheter includes a shield tube fitted over a portion of the proximal end of the catheter. The shield tube is designated 406 in Fig. 42A, and is described on page 34, lines 10-12 and page 37, lines 19-22 of the Specification. The Examiner asserts that Claim 40 is unpatentable over Waksman et al. and Mawad. The Examiner cites Waksman et al. for teaching the provision of radioactive shielding in the carriage 48 which is within the transfer device. There is no suggestion in Waksman et al. for the provision of any additional radioactive shielding on the catheter. Mawad is cited for the disclosure of a radioactive wire that has an outer buffer layer of platinum or other high atomic number metal in order to attenuate the radiation delivered by the wire. Mawad, when combined with Waksman et al., suggests shielding the treatment elements of Waksman et al. -- not, as called for by Claim 40, shielding a proximal portion of the delivery catheter. By shielding the catheter rather than the treatment elements, the user is protected against unnecessary exposure to radiation without dapening the radioactivity of the treatment elements. As such, applicant submits that Claim 40 is not rendered unpatentable over the combination of Waksman et al. and Mawad.

CONCLUSION

Based upon the foregoing, applicant respectfully submits that each of the pending claims is patentable over the prior art of record. As such, applicant respectfully requests the Examiner to reconsider and withdraw the rejections of these claims, and allow the application.

Respectfully submitted,



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VERSION WITH MARKINGS TO SHOW CHANGES MADE

20. (Amended) The catheter of Claim~~s 18~~ 19 wherein said detent comprises a cantilever arm axially extending from said connector.

22. (Amended) The catheter of Claim 21 further comprising at least one radiopaque marker for aligning said distal end and the at least one treating element with the selected site of the body of a patient, said radiopaque marker being located within said first lumen at said distal end and providing a fluid flow path between said first and second lumen.